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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,642

06/20/2006

Timothy John Norman

07-1007-WO-US

3724

20306

7590

02/25/2009

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/583,642</p>	<p>Applicant(s) NORMAN, TIMOTHY JOHN</p>	
	<p>Examiner PAUL DICKINSON</p>	<p>Art Unit 1618</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1 and 8.
Claim(s) withdrawn from consideration: 2-4, 6-7, and 9-10.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/PAUL DICKINSON/
Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: Regarding the election of species, Applicant argues that claims 2, 7, and 10 read on the elected species and should be examined on the merits. Applicant's arguments have been fully considered but are not found persuasive. As stated in the office action mailed 4/15/2008, no prior art was found directed to the elected species (see pages 2 and 6). Claims 2-4, 6-7, and 9-10 are withdrawn as not reading on Applicant's elected species nor that cited in the prior art rejection of record. "...should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species." MPEP § 821.

The rejection of claims 1 and 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained.

Applicant argues that the specification defines residue as "that portion of a polymer or of a biologically active moiety which remains after it has undergone a substitution reaction as such terminology is familiar to the person skill in the art". Applicant provides further definitions of residue. Applicant argues that to those skilled in the arts of chemistry and biochemistry, the term "residue of a polyethylene glycol (PEG) molecule" would be understood to mean a portion of a polyethylene glycol (PEG) molecule that can be identified as being derived from a polyethylene glycol building block, or one or more ethylene glycol monomers, less the hydrogen or oxygen atoms that are lost during polymerization.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner appreciates the definitions cited in the reply. However, none of these definitions are limiting. The Examiner must give the claims their broadest reasonable interpretation. Applicant's specification defines residue as "that portion of a polymer or of a biologically active moiety which remains after it has undergone a substitution reaction." This definition does not indicate how the base molecule may be changed while remaining a residue. The compound cited by the Examiner in the previous action is a polyethylene glycol molecule:

Wherein PEG is polyethylene glycol and X1 and X2 are linkers. If this polyethylene glycol molecule underwent a substitution reaction, one product could be the terminal maleimide unit. Thus, according to the instant specification's definition of the term residue, the terminal maleimide unit could be considered a residue of this polyethylene glycol molecule. This reasoning is based on Applicant's own definition. Applicant argues that the terminal maleimide unit would not be recognized by those skilled in the art as a PEG residue, because it cannot be identified as having been derived from a PEG molecule. This is not found persuasive. Such recognition of the parent compound in the structure of the residue is not a requisite in Applicant's definition. Giving the claims their broadest reasonable interpretation, the specification's definition of residue as "that portion of a polymer or of a biologically active moiety which remains after it has undergone a substitution reaction" is consistent with the above analysis, as after an appropriate substitution reaction, the maleimide would remain. Thus, in the broadest reasonable interpretation, a "residue of a polyethylene glycol molecule" may be a maleimide. Claim 1 also recites "residue of polyclonal, monoclonal, multi-valent, multi-specific, humanized or chimeric antibody, a single chain antibody, a Fab' fragment, a Fab' or F(ab')₂ fragment, or an epitope-binding fragment" and also "maleimide residue". These genera, along with "residue of a polyethylene glycol (PEG) molecule", lack written description as they recite the residue of a parent compound, or the residue of a fragment of a parent compound. The residues encompassed by these genera are highly variant and the Applicant has not provided a description of the structural relationship of the residues to the parent compounds.

The rejection of claim 1 under 35 U.S.C. 102(b) as being unpatentable over Norman et al (J. Chem. Soc., Chem. Commun., 1995) is maintained.

Given the myriad of compounds encompassed by the term "residue", the Examiner maintains that 1-pentyl-1H-pyrrole-2,5-dione and OC(CH₃)₃ are residues of polyethylene glycol molecules. Regarding Z1, Norman et al discloses reaction of the maleimide with antigen binding fragments of monoclonal antibodies through the maleimide group (see entire document). Regarding B2, the Examiner stated previously that the broadest reasonable interpretation of -CONH- would be the one in which the functional group was oriented in either the fashion wherein the carbon atom is bonded to Y2 and the nitrogen atom is bonded to V2, or the reverse (see office action mailed 11/16/2008, page 4). Applicant argues that the instant specification discloses separate embodiments of the invention wherein A1 and A2 may be -CONH- or -NHCO-. Applicant argues that no embodiments wherein B2 is -NHCO- are disclosed. Accordingly, -CONH- and -NHCO- are not interchangeable and each corresponds to a different orientation within the molecule. The presently claimed -CONH- orientation cannot be construed to encompass the -NHCO- orientation disclosed by Norman et al. This is not found persuasive. There is nothing in the instant claim that indicates that -NHCO- is connected in the fashion argued by the Applicant. In other words, if -CONH- and -NHCO- are not interchangeable and each corresponds to a different orientation within the molecule, which formula refers to which orientation is not specified in the claim nor in the specification. Accordingly, the broadest reasonable interpretation of "B2.... independently represent -CONH-..." is the one wherein the group adopts one of two possible orientations: where the carbon atom is bonded to Y2 and the nitrogen atom is bonded to V2, or the reverse. The Examiner maintains that the compound of Norman et al reads on the compound disclosed in instant claim 1 as follows:

P1=1-pentyl-1H-pyrrole-2,5-dione

A1=CONH

W1=(CH₂)₂

X1=N

V1=covalent bond

B1=CO

Y1=(CH₂)₅
L1=maleimide
Z1=Fab' fragment

M1=(CH₂)₁

P2=OC(CH₃)₃
A2=CONH
W2=(CH₂)₄
X2=CH
V2=covalent bond
B2=NHCO
Y2=(CH₂)₅
L2=maleimide
Z2=Fab' fragment

n=0